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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/645,715	08/20/2003	George V. Guittard	AR02366USACON3	8447

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PHILIP S. JOHNSON
JOHNSON & JOHNSON
ONE JOHNSON & JOHNSON PLAZA
NEW BRUNSWICK, NJ 08933-7003

EXAMINER	
GEORGE, KONATA M	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 07/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/645,715	GUITTARD ET AL.	
	Examiner	Art Unit	
	Konata M. George	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 32-48 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 32-48 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 32-48 are pending in this application.

Information Disclosure Statement

1. The information disclosure statement (IDS) submitted on January 7, 2004 and August 20, 2003 was noted and the submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the examiner has considered the information disclosure statement.

Claim Objections

2. Claims 32 and 40 contain language that is not commonly recited as claim language. The word "set" is used to describe a group, examiner would like to request that the word "set" be changed to "group".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 32 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3 and 4 of U.S. Patent No. 5,674,895. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending application is directed towards a dosage form comprising oxybutynin or its pharmaceutically acceptable salt in a dosage amount of 5 mg to 250 mg and the '895 patent teaches a composition comprising 1ng to 450 mg of oxybutynin and additional excipients. It is the position of the examiner that since the both the pending application and the patent contain administering oxybutynin having overlapping dosage ranges, it would have been obvious to one of ordinary skill in the art to add excipients to the dosage form of the pending application to help facilitate the production and delivering of the drug.

4. Claims 40 and 48 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 5,840,754. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the '754 patent are directed toward a method reducing the incidence of side effects associated with oxybutynin treatment by administering the drug over a twenty-four hour period. The difference between the pending application and the

'754 patent is the recitation of a dosage amount. It is the position of the examiner that the dosage amount is a limitation that would be routinely determined by one of ordinary skill in the art as part of the process of normal optimization to achieve the desired results of reducing the incidence of side effects associated with oxybutynin treatment.

5. Claims 32-39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,912,268. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending application is directed towards a dosage form comprising oxybutynin or its pharmaceutically acceptable salt in a dosage amount of 5 mg to 250 mg and the '268 patent also teaches a dosage form comprising oxybutynin or its pharmaceutically acceptable salt contained in a dosage amount of 240 ng to 650 mg. The dosage form also contains hydroxypropyl alkyl cellulose and polyalkylene oxide. It is the position of the examiner that since the pending application and the patent are directed towards the same invention then it is not patentability distinct from each other.

6. Claims 32, 36, 40 and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-10 and 16-21 of U.S. Patent No. 6,124,355. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the '355 patent are directed towards an oral dosage form

comprising oxybutynin in the form of a tablet used to treat incontinence in patient in need thereof. Both the pending application and the '355 have an overlapping dosage range of 5 mg to 20 mg. It is the position of the examiner that since the pending application and the patent are directed towards the same invention then it is not patentability distinct from each other.

7. Claims 40-47 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 4 and 5 of U.S. Patent No. 6,262,115 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the pending application and the '115 patent are directed towards a method of management of incontinence comprising admitting orally a dosage form comprising oxybutynin or its pharmaceutically acceptable salt. It is the position of the examiner that since both the pending application and the '115 patent teaches the same method, using the same drug, with an overlapping dosage range (i.e. 5 mg to 250 mg) then there is no patentable distinction between the pending application and the '115 patent.

8. Claims 32 and 40 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 32 of copending Application No. 09/785,805. Although the conflicting claims are not identical, they are not patentably distinct from each other because both pending applications are directed to a composition and a method of

managing incontinence in a patient by administering an oral dosage form of oxybutynin. Since both pending applications contain an overlapping dosage range and drawn to the same composition and method, there is no patentable distinction between the both pending applications.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kodama KK (JP 406009388A).

Kodama KK discloses a sustain release of a pharmaceutical preparation characterized by blending a gel-forming substance such as hydroxypropyl methylcellulose, >C12 higher alcohols in a pharmaceutical composition containing oxybutynin hydrochloride. The prior art does not disclose the dosage amount as claimed by applicant.

It is the position of the examiner that dosage amount is a limitation the would be routinely determined by one of ordinary skill in the art, through minimal experimentation, as being suitable, absent the presentation of some unusual

and/or unexpected result. These results must be those that accrue from the specific limitations.

Conclusion

10. Claims 32- 48 are rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George
Patent Examiner
Art Unit 1616